For the past two weeks, there has been intense media coverage of research conducted by a UNC employee on literacy rates among student-athletes. These reports contained numerous errors and misrepresentations with regard to the IRB status of this research. The following statement was prepared by the Office of Human Research Ethics, which oversees the IRBs, to respond to media inquiries and address inaccuracies in prior reports:

January 21, 2014

We did not suspend approval for Mary Willingham’s research. She has never had Institutional Review Board (IRB) approval, so there was no approval to suspend.

In 2008, Ms. Willingham requested a “Determination Whether Research or Similar Activities Require IRB Approval” (which is both the label and purpose of the form she submitted), and that is what she received. Based on the information provided, most importantly the certification that she and other researchers would be working solely with de-identified data, we determined that her proposed activity did not involve human subjects (as defined by federal regulations). “De-identified” does not mean that researchers will protect the identity of their subjects and not disclose them publicly (which is an obvious expectation for virtually all research)... but means that the researchers themselves do not have access to names or codes that would allow them to re-identify individual subjects. Many research projects are conducted in this manner and, because Ms. Willingham stipulated this was how her study would be done, it did not require IRB approval. This determination has been consistently misrepresented as an IRB or institutional approval, but this is not accurate.

On Jan 16, my office took action to correct the prior determination, as we would with any research project if/when it becomes clear that we were working with faulty or incomplete information. There should be no implication that Ms. Willingham was singled out, or that her provision of an identifiable dataset to the Provost was a violation that triggered our action. Rather, it was our realization that the researchers had, in fact, been in possession of named data all along; this was confirmed by multiple sources, including Ms. Willingham’s own statements via the press. This constituted new information that contradicted her earlier statements to the IRB, and we acted accordingly.

There should also be no implication that my office was pressured to take this action. The IRB at UNC operates with a very high degree of independence and authority, as it was intended. As example, neither I nor my staff have ever heard from or communicated with Provost Dean on this (or any other) matter; I met him for the first time on Jan 17, for 30 seconds, when I attended the Faculty Council meeting in case questions arose that required my input.

In terms of the process going forward, Ms. Willingham has the same opportunity as any employee to apply for IRB approval of her research. This would be subject to the same review as any study, which will address issues of informed consent, access to records, and compliance with federal, state and university policies.

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